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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/949,758	10/14/97	GOLDENBERG	D 018733/0808

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EXAMINER
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MERTZ, P

ART UNIT	PAPER NUMBER
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1646

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DATE MAILED:

02/18/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/28/98

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) 16-19, 22 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 6-8, 9-15, 20-21 is/are rejected.

☒ Claim(s) 2-5 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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### **DETAILED ACTION**

1. Claims 16-19 are withdrawn from further consideration by the Examiner, as being drawn to a non-elected invention (Paper No.6, 9/28/98). Claims 2-14, amended claims 1 and 15 and new claims 20-21 (Paper No. 7, 12/28/98), are under consideration.

2. Applicants compliance with sequence rules is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 7, 12/28/98:

(I) the rejection of claims 1 and 6 under 35 U.S.C. 102(b) as being anticipated by Verheul et al. (WO 92/00762).

(ii) the rejection of claim 3 under 35 U.S.C. 103(a) as being unpatentable over Verheul et al. (WO 92/00762) as applied to claims 1 and 6 above, and further in view of Anderson et al. (1995).

4. Applicant's arguments filed in Paper No. 7 (12/28/98), have been fully considered but were deemed persuasive in part. The issues remaining and new issues, are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim objections***

6. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim i.e. claim 1. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

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***Claim Rejections - 35 USC § 112***

7. Claims 8-15 and 20-21 are rejected under 35 U.S.C. 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 4-5 of the previous Office action (Paper No. 6, 9/28/98).

Applicants argue that the present specification references "a fairly large and growing body of experience in the use of monoclonal antibodies (mAbs) for the therapy of lymphoma", and have cited LL2 labeled with <sup>131</sup>I in this regard. However, contrary to Applicants arguments, unless Applicants can show differences in expression of cell markers specific to malignant cells, and selective killing of malignant cells without killing those cells (expressing specific markers), that are required for normal function of the immune system, the 35 U.S.C. 112, first paragraph rejection is being maintained.

8. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is vague and indefinite because it recites "is higher than expression of ...", which is a relative term and it is unclear how much higher the expression must be for the difference in expression to be consequential.

***Claim Rejections - 35 USC § 102***

9. Claims 1, 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Mallinckrodt Medical, Inc. (WO 94/07535).

This rejection is maintained for reasons of record set forth at page 6 of the previous Office action (Paper No. 6, 9/28/98).

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Applicants argue that it is incorrect that Mallinckrodt Medical “teach a conjugate of a therapeutic radionuclide and a cell-specific cytokine, IL-8”, and to the contrary, Mallinckrodt Medical is directed to “a labeled CXC chemokine [utilized] to image a target site in an animal’s body” and does not suggest conjugates with a therapeutic radionuclide. However, contrary to applicants arguments, a labeled CXC chemokine with a radioactive agent as a label to be used as a diagnostic, (see page 5, lines 4-11) can be therapeutic if too much of the radionuclide conjugated to said cytokine is used.

***Conclusion***

10. No claims are allowed.

Claims 3-5 are objected to for being dependent on a rejected base claim.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Prema Mertz*  
Prema Mertz Ph.D.  
Patent Examiner  
Art Unit 1646  
January 29, 1999